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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,401	05/12/2005	Filip Arnaut	VANM199.005APC	6305
29995 7590 05/28/2009 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614				
EXAMINER				
BADR, HAMID R				
ART UNIT		PAPER NUMBER		
1794				
NOTIFICATION DATE		DELIVERY MODE		
05/28/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/510,401

Applicant(s)

ARNAUT ET AL.

Examiner

HAMID R. BADR

Art Unit

1794

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 23-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 23-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Applicants' amendment filed on 2/16/2009 is acknowledged.

Claims 1-18 and 23-32 are being considered on the merits.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 6-7, 9-10, 13-16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Klingenberg et al. (DD 156,714 A; hereinafter R1).

3. R1 teaches preparing a heat stable thermitase from *Thermoactinomyces vulgaris*. This enzyme is a proteinase for weakening gluten in the preparation of wafers, other cereal and bakery products (Page 1, paragraph 1 and Claim 1).

4. Although there is no explicit disclosure of preventing or retarding staling during the baking process of the bakery products, given that R1 discloses method and improver identical to that presently claimed, it is clear that the method and the improver would inherently prevent or retard staling during the baking process of the bakery products.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3-4, 8, 12, 17, 25, 27, and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klingenberg et al. (DD 156,714 A; hereinafter R1) in view of Olesen et al. (US 6,110,508; hereinafter R2)

7. R1 teaches preparing a heat stable thermitase from *Thermoactinomyces vulgaris*. This enzyme is a proteinase for weakening gluten in the preparation of wafers, other cereal and bakery products (Page 1, paragraph 1 and Claim 1).

8. Regarding claim 3, it is obvious that a thermostable enzyme with a high optimum temperature for activity will be much more active than the same enzyme at much lower temperature e.g. 25C. The property of a much higher activity of a thermostable enzyme at higher temperature compared to the activity of the same enzyme at lower temperature will be inherent in the enzyme.

R1 is silent regarding addition of other enzymes and emulsifier to the dough.

9. R2 discloses the use of lipase together with other enzymes such as cellulase, hemicellulase, xylanase, glucose oxidase, peroxidase, amyloglucosidase, and alpha-amylase in bakery products including bread (Col. 5, lines 33-46). Bacterial alpha-amylase is known in the art and is a thermostable enzyme. It would be obvious to those

of skill in the art to select a thermostable amylase such as a bacterial amylase to add to the dough formulations.

20. R2 teaches using emulsifiers such as mono and diglycerides, diacetyl tartaric acid esters of mono- and diglycerides (DATEM), sugar esters of fatty acids, lactic acid esters of monoglycerides, polyoxyethylene stearates, phospholipids and lecithin in their dough improver (Col. 6, lines 46-56). These emulsifiers are used to improve dough extensibility as well as the consistency and storage stability of the bread.

21. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use a thermostable protease as taught by R1 and include the improving enzymes and emulsifiers taught by R2 to receive the benefits of the dough improving properties of such enzymes and emulsifiers to prevent or retard staling in baked goods. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success.

10. Claims 7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over R1 in view of Terada et al. (US 5,124,261; hereinafter R3) and Chernoglazov et al. (RU 2,177,799; hereinafter R4).

11. R1 teaches preparing a heat stable thermitase from *Thermoactinomyces vulgaris* as described above. R1 is silent regarding protease of *Thermus aquaticus* and Keratinase of *Bacillus leicheniformis*.

12. R3 discloses a process for the production of aqualysin I employing a genetic engineering procedure by cultivation of *Thermus aquaticus* (Col. 1, lines 34-52 and Col. 8, lines 31-51).

13. R3 is silent regarding a keratinase enzyme.

14. R4 discloses a new keratinase from *Bacillus licheniformis*. The keratinase can be used in the food industry (Abstract).

16. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of R1 by including the protease and keratinase taught by R3 and R4. One would do so to receive the benefits of a thermostable protease and keratinase at least at the early stages of baking where the temperature is high enough for the activation of these thermostable enzymes and yet not that high to denature such enzymes.. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success.

15. Claims 2, 5, 11, 23, 24, 26, and 28-29 rejected under 35 U.S.C. 103(a) as being unpatentable over R1 as applied above, further in view of Stetter (US 5,714,373; hereinafter R5).

16. R1 teaches preparing a heat stable thermitase from *Thermoactinomyces vulgaris* as described above.

17. R5 discloses the isolation and identification of a thermostable protease from *Thermococcus* which has an optimum temperature range between 60C and 90C (col.7, lines 38-41).

18. It would have been obvious to one of ordinary skill in the art to use proteases which have an optimum range of activity in the 60C-90C.

19. Claims 5 and 26 are obvious due to the fact that serine proteases have a serine residue at the active site which acts as a nucleophilic residue in proteolytic activities, being active at neutral or alkaline pH.

20. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to employ the thermostable proteases from various sources as taught by R1, R3, R4 and use them at optimally at 60-90C as taught by R5.

Response to Arguments

Applicants' arguments have been thoroughly reviewed. They are not deemed persuasive for the following reasons.

1. Applicants argue that Klingenberg et al. (R1) neither discloses nor suggests that this thermitase can be used to prevent or retard staling during the baking process of the bakery products.

a. R1 teaches the method for producing the thermostable protease from the source as presently claimed. R1 discloses that Thermitase is used for gluten breakdown in the production of processed foodstuff, waffles and bakery products.

In the art of baking, the anti-staling compositions employ protease and amylase. The protease acts on the gluten component of the dough. The hydrolysis of gluten in coordination with starch hydrolysis will bring about the retardation of staling in bread

and other baked products. Although there is no explicit disclosure of preventing or retarding staling during the baking process of the bakery products as disclosed by R1, however, the break down of gluten (proteolytic hydrolysis of gluten) will cause the softening of the bread crumb which in turn will help retard the staling of bread.

Applicants argument that R1 teaches only a crude preparation containing the Therminase is not relevant because the isolation and purification of Therminase is not a requirement as presently claimed. On the other hand, R1 clarifies that crude or partially purified preparations are useful in the food industry and that highly purified grades are useful as fine biochemicals. The amount of Thermitase is not discloses, however, when gluten breakdown in a product is indicated, it is implied that enough protease is added to effectuate the hydrolysis of gluten.

2. Applicants argue that while Olesen et al. (R2) discloses that a protease can be added for gluten weakening. However this reference does not teach thermostable protease.

a. R2 is used to disclose the use of thermostable amylase in bread improving compositions. Incorporation of a thermostable protease is disclosed by R1 (see above). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

3. Applicants argue that Terada et al. discloses a heat resistant protease from a source which is presently claimed and that the enzyme is used in detergents and a

component of bioreactors. They also argue that Chernoglazov disclose the keratinase which can be used in the food industry and that Stetter discloses production of thermostable protease from a source which is presently claimed. This enzyme does not teach that such an enzyme can be used in bakery products.

a. Terada, Chernoglazov and Stetter are secondary references. However, note that while Terada and Chernoglazov or Stetter do not disclose all the features of the present claimed invention, Terada and Chernoglazov or Stetter are used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention.

Further, since the inclusion of a thermostable protease is disclosed by R1, the inclusion of other thermostable proteases in bakery products would be obvious to an artisan. They are all being added for the purpose of hydrolyzing the gluten in the dough. The thermostable proteases as disclosed by Terada, Chernoglazov and Stetter are being presently claimed.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
Art Unit 1794

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